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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,216	SEINFELD, HUGO	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15 and 19-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 19-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Status of Application/Amendment/Claims

1. Claims 1-14 and 16-18 were cancelled by Applicant in the communications filed 06/02/2002 and 3/22/2005. Claims 21-37 were newly added by Applicant in the communication filed 3/22/2005. Claims 15 and 19-37 are pending and under examination in this application.

Applicant's response filed 3/22/2005 has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed 11/19/2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

Response to Arguments

2. Applicant has argued that references FR 2 713 487 and DE 25 47 696 cited in the IDS of February 6, 2004, which were not considered by the Examiner in the Action mailed 11/19/2004, should be considered because these references were cited in the International Search Report by a foreign patent office in a counterpart foreign application and the indication of relevance is provided therein (pg. 5, 3rd thru 6th full paragraphs). The examiner believes, for the purposes of clarification, that the reference

to the IDS of February 6, 2004 was intended to be a reference to the IDS of February 6, 2002. In regards to the IDS of February 6, 2002, the copy of the international search report filed in the instant application was inadvertently overlooked in Action mailed 11/19/2004. Therefore, references FR 2 713 487 and DE 25 47 696, cited on the PTO Form 1449 filed 02/06/2002, have been considered and made of record.

Claim Rejections - 35 USC § 112

3. Claims 15 and 20 are maintained as rejected and claims 23-24, 27-29, 31-33 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, claim 15 recites, "administering to the subject an active amount of at least 0.1mg of xenogeneic oligo- and/or polyribonucleotides per unit dose" and claim 20 recites, "administering an active amount of at least 0.1mg xenogeneic oligo- and/or polyribonucleotides in an anhydrous preparation per unit dose." In the instant case, the metes and bounds of what is encompassed by "an active amount" cannot be determined. The skilled artisan cannot determine, for example, what is required to be administered by "an active amount of at least 0.1 mg per unit dose" because there is no indication in the claim language as to what part of the unit dose is the active part. Therefore, the skilled artisan cannot determine what constitutes "an active amount... per unit dose" as required by the claim.

Claims 23-24, 27-29, 31-33 and 36-37 are indefinite for the same reasons as applied to claims 15 and 20 above because they depend from either claim 15 or 20.

4. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "the pharmaceutical composition" in line 3. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites, "comprising administering an active amount of at least 0.1 mg of xenogeneic oligo- and/or polyribonucleotides in an anhydrous preparation per dose unit is administered once per recurrence to the subject" and is therefore not a complete sentence. Appropriate correction is required.

6. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the limitation "the subject" in line. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, the skilled artisan cannot determine the

metes and bounds of what is being claimed because the claim is drawn to a method of treatment by administering "xenophic" oligo- and/or polyribonucleotides." However, the meaning of "xenophic" cannot be determined because this word does not appear in the specification as filed, does not appear in the dictionary (please see the results of several online dictionary searches attached to this Action) and is not art recognized terminology in the relevant scientific fields of biology or biotechnology.

8. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 is not a complete sentence. Appropriate correction is required.

Response to Arguments

9. Applicant's amendments to claims 15, 19 and 20, filed 03/22/2005, are sufficient to overcome, in part, the previous grounds of rejection under 35 U.S.C. § 112 2nd paragraph. Applicant's amendments, in removing the terminology, "and higher" from the instant claims have overcome the outstanding grounds of rejection which considered that the language of the instant claims failed to set an upper limit on the dose of the xenogeneic oligo- and/or polyribonucleotides of the invention that was to be administered. However, applicants arguments and amendments are not considered persuasive in regards to the outstanding grounds of rejection which considers that the

metes and bounds of what is being claimed by an "active amount" cannot be determined (as set forth in the prior Action and above).

10. Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 29-31 are drawn to methods of treatment comprising administering xenogeneic oligo- and or polyribonucleotides wherein said xenogeneic oligo- and or polyribonucleotides are obtained directly from a plant, an animal or a unicellular organism. The claim limitation, "are obtained directly from a plant, an animal or a unicellular organism" was newly introduced by amendment in the communication filed 03/22/2005. However, no support for this claim limitation, in the context of this invention, could be located in the specification as filed. The specification as filed indicates preferences in regards to the origin of the xenogeneic oligo- and or polyribonucleotides of the invention (see pg. 2, lines 27-37 bridge to pg. 3, lines 1-6), but does not contemplate, either specifically or inherently, the instant claim limitation wherein the xenogeneic oligo- and or polyribonucleotides of the invention are required to be "obtained directly from a plant, an animal or a unicellular organism," as now claimed.

11. Claims 15 and 20 are maintained as rejected and claims 19 and 21-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the Action mailed 11/19/2004 and reiterated herein. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims are drawn to a broad genus of methods of treatment wherein any of a vast genus of xenogeneic oligo- and or polyribonucleotides are used to treat any and/or all infections caused by a large family of DNA containing viruses (the Herpesviridae) and/or a broad genus of skin tumors and to a method of treating lesions of the skin and/or mucosa caused by *Herpes simplex* or *Varicella zoster* as above. In the instant case, the breadth of the claimed genus of treatments that employ any xenogeneic oligo- and/or polyribonucleotides to treat any Herpesviridae infection or any skin tumors, as claimed, is extremely broad and reads on a vast number of xenogeneic oligo- and/or polynucleotide species that will function to treat of any of a vast number of infections caused by Herpesviridae viruses and/or skin tumors and a vast number of methods of treatment of using any xenogeneic oligo- and/or polyribonucleotides to treat lesions of the skin and/or mucosa caused by *Herpes simplex* or *Varicella zoster*.

The specification as filed discloses a single example of xenogeneic oligo- and or polyribonucleotides that will function in the method as claimed, only 2 strains of *Herpes simplex* infections that are treated and only a single example of a skin tumor (a

basalioma) that is treated by the method as claimed. The specification as filed indicates preferences in regards to the origin of the xenogeneic oligo- and or polyribonucleotides of the invention (see pg. 2, lines 27-37 bridge to pg. 3, lines 1-6), but does not provide a limiting definition of xenogeneic oligo- and or polyribonucleotides. The specification as filed provides general guidance as to what is encompassed by xenogeneic oligo- and/or polyribonucleotides of the invention but does not provide a disclosure of sufficiently detailed, relevant identifying characteristics of xenogeneic oligo- and or polyribonucleotides that will function in a method of treating any infection by any member of the Herpesviridae viral family or a method of treating any of the vast array of complex and multigenic dermal disorders that would be encompassed by any skin tumor or a method of treatment using any xenogeneic oligo- and/or polyribonucleotides to treat lesions of the skin and/or mucosa caused by *Herpes simplex* or *Varicella zoster*, as claimed. Therefore, the specification fails to provide sufficient evidence that applicant was in possession of the claimed invention. In particular, no adequate written description is provided of xenogeneic oligo- and or polyribonucleotides that will function to a provide treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor because the specification does not provide the specific structure of any particular xenogeneic oligo- and or polyribonucleotides that would correspond with the function of providing treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor.

Therefore, the disclosure of the specification fails to provide a) specific guidance concerning what distinguishing identifying characteristic of the claimed xenogeneic

oligo- and or polyribonucleotides that are required by the instant method, would correspond with the function of providing treatment commensurate with the scope of what is being claimed, and b) the structure of any particular xenogeneic oligo- and or polyribonucleotides that would correspond with the function of providing a treatment commensurate with the breadth of what is being claimed. The general guidance provided by the specification in regards to the xenogeneic oligo- and/or polyribonucleotides of the invention is insufficient to indicate possession because it does not provide the specific guidance required to reasonably lead one of skill in the art to the instant invention as claimed. What is the specific structure of the xenogeneic oligo- and/or polyribonucleotides that would correspond with the function as claimed, of providing a treatment for any infection caused by any member of the Herpesviridae family of viruses and/or any skin tumor, for example, or of being any xenogeneic oligo- and/or polyribonucleotides to treat lesions of the skin and/or mucosa caused by *Herpes simplex* or *Varicella zoster*?

MPEP § 2163[R-2] I. states:

> To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.
>
> The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.
>
> Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See,

> e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").
>
> An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

Therefore, Applicant has not provided adequate written description of their invention because Applicant has not shown how their invention was "ready for patenting" such as by the disclosure of the structure of xenogeneic oligo- and/or polyribonucleotides that can be any xenogeneic oligo- and/or polyribonucleotides that function in a method of treatment as claimed, that shows that the claimed invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed methods of treatment, commensurate with what is now claimed.

Response to Arguments

Applicant's arguments filed 03/22/2005 have been fully considered but they are not persuasive. Applicant has argued, that the medicament is quite simply made by an RNA preparation obtained from a xenogeneic organism, has pointed to the specification to indicate the contemplation of preferred organisms and stated that the examples of the specification generally describe recovery from a yeast but that the specification clearly sets forth a broad range of sources as contemplated and described (pg. 6, 1st full paragraph). However, the claims are not drawn to a medicament but to a method of

treatment comprising administering xenogeneic oligo- and or polyribonucleotides that will function as claimed. In the instant case, it is unclear how Applicants arguments address the outstanding grounds of rejection which considers that the general guidance provided by the specification is insufficient to provide an adequate written description of the invention because it does not point to a specific structure that corresponds with the function as claimed and does not provide a disclosure of sufficiently detailed, relevant identifying characteristics of xenogeneic oligo- and or polyribonucleotides that will function in a method of treatment, commensurate with what is claimed.

Applicant has argued that, "With respect to the Herpesviridae family, it is a relatively small family consisting of *Herpes simplex* and *Herpes genitalis*, and, although these herpes viruses can cause so different diseases, the same herpes viruses are concerned. A declaration will be provided along with two test reports using *Herpes labialis* (HSV 1) and *Herpes genitalis* (HSV 2) which clearly support the claimed effects of the invention. Clearly, this family is described in the present application, as are the xenogenic oligo-and/or polynucleotides (pg. 6, 2nd full paragraph). However, with respect to the Herpesviridae family, a review of the taxonomy browser at the National Center for Biotechnology Information (Entrez) indicates that this family, which Applicant has characterized as relatively small, consists of at least 150 viruses in addition to *Herpes simplex* and *Herpes genitalis* (please see printout of NCBI Taxonomy Browser page: Herpesviridae, viewed by the Examiner on 6/01/2005 and attached to the back of this action). Therefore, the description of a method of treating 2 species of the Herpesviridae family does not constitute a description of a method of treating a

representative number of a genus. In regards to the declaration referred to above, while the data are consistent with the treatment of *Herpes simplex* and *Herpes genitalis* using the instantly claimed method, a declaration that provides description of 2 particular embodiments is not sufficient to overcome the outstanding grounds of rejection for lack of adequate written description because the declaration as filed does not address the grounds of rejection which considers that Applicant was not in possession of the instant invention commensurate with the breadth of what is claimed, that is a genus of method of treating any Herpesviridae infection.

Applicant has argued that, "With respect to skim tumors, basaliomas are provided as a species of tumor which may be treated in accordance with the present invention, but one skilled in the art would understand that this is intended to include other skin tumors treatable by the claimed methods (pg. 6, 3rd full paragraph). However, this argument does not address the outstanding grounds of rejection because the disclosure of single example of a single treatment of a single type of skin tumor is insufficient to indicate that Applicant's was in possession of a broadly claimed genus of method of treating any skin tumor due to any cause, commensurate with what is now claimed.

Applicant has argued that the invention works with RNA obtained from xenogenic tissues according to the methods given and that no separation of the obtained products according to any structural properties is necessary to obtain a preparation having the given properties and that the invention is adequately described for the provisions of 35 U.S.C. § 112, first paragraph. However, the basis of the outstanding written description

rejection considers that the specification as filed provides only general guidance as to what is encompassed by xenogeneic oligo- and/or polyribonucleotides of the invention, not a disclosure of sufficiently detailed, relevant identifying characteristics of methods of treatment that require the claimed xenogeneic oligo- and or polyribonucleotides. The claims are drawn to methods that require the use of xenogeneic oligo- and or polyribonucleotides, not to methods of treatment comprising administering nucleic acid extracts or preparations. Therefore, in order to satisfy the requirement for an adequate written description of the claimed xenogeneic oligo- and or polyribonucleotides, Applicant must provide or point to a structure that corresponds with the function of the claimed xenogeneic oligo- and or polyribonucleotides in the instantly claimed methods. In support of this, Applicants attention is drawn to US Patent 5, 989, 904 (Das et al.) who disclose that the antiviral properties of oligo- and polyribonucleotides that are extracted from yeast, set forth as a preferred source of the xenogeneic oligo- and or polyribonucleotides of the instant invention, are due to the presence of a specific structure (nucleotide sequence) that is complementary to a viral IRES site, said structure being required for viral inhibition (see entire document, in particular cols. 9-10). Applicant has not pointed to or provided a description of such a structure of the instantly claimed xenogeneic oligo- and or polyribonucleotides, although such a structure is clearly required for the xenogeneic oligo- and or polyribonucleotides to function as claimed. Therefore, although the description of the specification provides several examples of oligo- and or polyribonucleotide extracts and preparations that will function to treat *Herpes simplex* viral infection, it fails to provide sufficient evidence that applicant

was in possession of the claimed xenogeneic oligo- and or polyribonucleotides which are required to function in the instantly claimed methods of treatment, commensurate with the vast breadth of what is now claimed.

Claim Rejections - 35 USC § 102

12. Claims 15 and 20 remain rejected and claims 21, 23, 27, 29, 31-32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. (WO 93/23569).

The invention as set forth in claims 15 and 20 is drawn a method of treating infections by Herpesviridae and/or skin tumors comprising administering an active amount of at least 0.1 mg of xenogeneic oligo- and or polyribonucleotides per unit dose (claim 15) wherein said xenogeneic oligo- and or polyribonucleotides are administered topically (claim 23) wherein said xenogeneic oligo- and or polyribonucleotides are obtained directly from a plant, an animal or a unicellular organism (claim 29) wherein the directly obtained xenogeneic oligo- and or polyribonucleotides are administered topically (claim 32). The method set forth in claim 20, although rendered indefinite by the instant claim language, is interpreted herein for the purposes of prior art to read on a method of treating infections by Herpesviridae and/or skin tumors comprising administering an active amount of at least 0.1 mg of xenogeneic oligo- and or polyribonucleotides per unit dose in an anhydrous preparation wherein the unit dose is administered once per recurrence wherein said xenogeneic oligo- and or polyribonucleotides are administered topically (claim 27) wherein said xenogeneic oligo-

and or polyribonucleotides are obtained directly from a plant, an animal or a unicellular organism (claim 31) wherein the directly obtained xenogeneic oligo- and or polyribonucleotides are administered topically (claim 36). Claim 21 is included in this rejection in the event that Applicant intended the term "xenophic" as it now appears in the claim, to recite, "xenogeneic" in accordance with the majority of the claims as instantly presented.

Draper et al. disclose a method for treatment of a virus caused disease by administering to a patient an enzymatic RNA molecule (pg. 4, lines 34-36) wherein the virus can be a herpes virus (pg. 71, example 10) and the ribozyme can be produced in high yield by expressing the ribozyme from a vector in a bacterial or eukaryotic cell (pg. 80, lines 4-8). These ribozymes would therefore constitute xenogeneic oligoribonucleotides in that they originate from an organism different from the one to be treated and are obtained directly from that organism (as defined by applicant on page 2 of the specification as filed). The ribozymes of Draper et al. can be formulated for topical administration with oleic acid in a liposome (thereby constituting an anhydrous preparation) (pg. 186, lines 30-37 bridge to the 1st paragraph of pg. 187) and the dosage can be between 100-200 mg/kg body weight/day, thereby constituting an active amount of at least 0.1 mg. The duration of the treatment of Draper et al. can extend continuously thru the course of the disease symptoms, thereby constituting a single administration per recurrence (pg. 191, lines 1-18).

Therefore, Draper et al. anticipate the instant invention as set forth in claims 15, 20, 21, 23, 27, 29, 31-32 and 36.

Response to Arguments

13. Applicant's arguments filed 11/19/2004 have been fully considered but they are not persuasive. Applicant has argued generally that Draper et al. concerns the use of ribozymes for treating viruses, something fundamentally different from the instantly claimed xenogeneic oligo- and or polyribonucleotides according to the present invention because no ribozymes are present in the preparations according to the invention (pg. 7, 2nd full paragraph). However, it is not clear what is intended by this line of argument because the disclosure of Draper et al. reads on the instant claims as currently presented and an argument that ribozymes are not present in the preparations according to the invention or that the use of ribozymes for treating viruses is somehow fundamentally different from the instantly claimed method of treating viruses with oligonucleotides does not address the particular points or point out supposed errors in the rejection of the instant claims set forth above.

Applicant has presented a discussion of how the RNA of the instant invention is preferably obtained and provided a general discussion concerning the ribozymes disclosed by Draper et al. as being artificial ribozymes, which can, according to Applicant, be distinguished from naturally occurring ribozymes (pg. 7, 3rd full paragraph). Applicant has concluded by arguing that the artificial, non-naturally occurring ribozymes of Draper et al. cannot be referred to as xenogenic, even when cell systems are used for producing them, because originating from a particular target organism is understood by the skilled person only to mean that corresponding RNAs

encoded by the genotype were not only produced in an organism but also stem from said organism evolutionarily and that therefore the ribozymes of Draper et al. are not xenogeneic oligo- and or polyribonucleotides (pg. 7, final paragraph bridge to pg. 8, 1st full paragraph).

However, contrary to Applicant's assertion, originating from a particular target organism is not understood by the skilled person only to mean that corresponding RNAs encoded by the genotype were not only produced in an organism but also stem from said organism evolutionarily. Moreover, the instant claims are not so limited. Rather, the instant claims are drawn methods of treatment comprising administering xenogeneic oligo- and or polyribonucleotides wherein, according to the specification as filed, "Xenogeneic in accordance with the present invention means that the ribonucleic acid originates from an organism different from the one to be treated therewith" and provides non limiting examples of preferred embodiments (pg. 2, lines 27-33). "Originate" as defined by Webster's II New Riverside University Dictionary, means: to bring or come into being (pg. 829, see attached photocopy). Therefore, the ribozymes of Draper et al. are considered to be xenogeneic oligo- and or polyribonucleotides because they are brought into being (expressed in and purified from bacteria and eukaryotes as disclosed above) from an organism different form the one to be treated therewith.

14. Claims 15 and 20 remain rejected and claims 21, 23, 27, 29, 31-32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Dirheimer et al. (U.S. Patent

4,213,970; 1st disclosed reference, the PTO-1449 filed 2/06/02, this application). The invention of claims 15, 20, 21, 23, 27, 29, 31-32 and 36 is as relied upon above.

Dirheimer et al. disclose and claim a method of treating viral infections in a warm blooded animal in need thereof comprising topically administering an antiviral composition comprising an effective amount (from 1-150 mg) of an antiviral eukaryotic transfer-ribonucleic acid (tRNA) (Claims 1-4, Col. 2, lines 30-42) wherein the viral infection to be treated can be herpes (Col. 2, line 33) wherein the preparation can be dissolved in sesame oil (interpreted here as being a disclosure of an anhydrous preparation) (col. 6, lines 58-62). The tRNA of Dirheimer et al. is extracted from yeast and is therefore "xenogeneic" as per Applicant's definition of xenogeneic on page 2 of the specification as filed (see quotation from the specification as cited in the rejection under Draper et al. above). The method of Dirheimer et al. is a method of treatment of an animal in need thereof and would therefore be a method wherein xenogeneic oligonucleotide and/or polyribonucleotides are administered once per recurrence because each recurrence would indicate that the animal was in need thereof.

Therefore, Dirheimer et al. anticipates the invention as set forth in claims 15, 20, 21, 23, 27, 29, 31-32 and 36. each and every aspect of the claimed invention.

Response to Arguments

15. Applicant's arguments filed 03/22/2005 have been fully considered but they are not persuasive. Applicant has argued that "Dirheimer et al. does not disclose that the composition is applied once per recurrence, therefore, each and every limitation of the

claim is not disclosed or suggested." However, contrary to this assertion, as set forth in the Action mailed 11/19/2004 in section 12 (pg. 10), Dirheimer et al. does disclose this limitation because the method of Dirheimer et al. is a method of treatment of an animal in need thereof and would inherently be a method wherein xenogeneic oligonucleotide and/or polyribonucleotides were administered once per recurrence, because in cases where treatment was effective, no additional treatment would be required and an additional recurrence would indicate that the animal was in need thereof.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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